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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,170

07/18/2003

Dana A. Oliver

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07/07/2006

GENZYME CORPORATION  
LEGAL DEPARTMENT  
15 PLEASANT ST CONNECTOR  
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EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,170	<b>Applicant(s)</b> OLIVER, DANA A.	
	<b>Examiner</b> Richard R. Shaffer	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

The proposed amendment filed on April 17<sup>th</sup>, 2006 to the abstract is acknowledged by the examiner. However, applicant failed to provide an clean version (free of any mark-ups) of the abstract on a separate sheet. Correction is required. See MPEP § 608.01(b).

The amendment to the written specification filed on April 17<sup>th</sup>, 2006 corrects for issues dealing with the drawings. The associated objections are now withdrawn.

### ***Claim Objections***

The amended claims filed on April 17<sup>th</sup>, 2006 are acknowledged and considered by the examiner in this Office Action. However, they are objected to for not having a separate and clean copy of the claims filed. In future replies, applicant will be held in abeyance for such procedural requirements.

### ***Claim Rejections - 35 USC § 112***

The claims have been clarified to remove the previous rejections under indefiniteness. The corresponding rejections are now withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummings et al (US Patent 6,322,563).

Cummings et al clearly anticipates (entire disclosure) a bioabsorbable fastener assembly comprising an applicator including a loading tip, carrier assembly removably mounted within the loading tip, cannula having an inner and outer diameter, and a surgical fastener (and surface feature) disposed within the cannula. Positive surface features (12) exist as well.

In its broadest reasonable interpretation, the “friction fit” of Cummings et al is a “clearance fit” of applicant because the fastener was still capable of being fit within the cannula and thus had “clearance.” As for the fluid being in communication with at least one positive surface feature, this is inherently the case with Cummings et al when considering surgery. Bodily fluids will excrete and be drawn into the device to fill any gaps present between the fastener and cannula **prior** to subsequent tack insertions. Further, the fluid will inherently form a meniscus inducing capillary force between the tack and cannula.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 5, 7, and 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al in view of *Using Parylene for Medical Substrate Coating* (<http://www.devicelink.com>).

The only differences present between applicants device and Cummings et al are a larger clearance between the tack and cannula and the use of a hydrophobic liquid. The website teaches that coatings for products including bone pins, prosthetic hardware, catheters, needles, medical probes, and various other implants are known in the art. Reasons include physical isolation from moisture, chemicals, and other substances; surface passivation; electrical insulation; tie-down of microscopic particles; and reduction of friction. It further goes on to say typical coatings are solvent-based liquid resins such as epoxies, silicones, acrylics, and urethanes and that these types of coatings exhibit liquid properties including: pooling, bridging between adjacent surfaces, and exhibiting meniscus forces.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to coat Cummings et al's device with a liquid such as silicone (as taught by <http://www.devicelink.com>) to reduce friction between the tack and cannula as well as to protect the tack from damage. Applicant is also directed to *In re Leshin*, 125 USPQ 416 discussing how it is within the general skill of a worker in the art to **select a known material** on the basis of its suitability for the intended use as a matter of obvious design choice.

In regard to claims 4, 5, 7, 12, 13, and 15 due to the nature of the Cummings et al device becoming jammed, an obvious design choice of increasing the clearance

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between the two components is known. Children are able to realize if two parts are sticking together due to a friction fit, one can either make the outer larger or the inner smaller. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed dimensions optimizations in order to retain a fit between the components while avoiding unwanted slippage.

### ***Response to Arguments***

Applicant's arguments filed April 17<sup>th</sup>, 2006 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

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*Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the reference at <http://www.devicelink.com> clearly teaches several materials and appropriate situations in which to use them. Even if it did not, as provided in this Office Action, the case law of *In re Leshin* holds that the mere selection of a material is within the general skill set of worker in the art.

In response to applicant's argument that examiner did arrive at a specific result, but rather a plurality of combinations from the <http://www.devicelink.com> reference and Cummings et al reference is not persuasive. The essence of obviousness is not that a specific result exists. It would have been equally obvious to one having ordinary skill in the art to use a different material as well.

In response to applicant's argument that a meniscus was not present in the Cummings et al's patent, this is not persuasive. A meniscus is inherent due to cohesive and adhesive properties of liquids. A liquid between the tack and cannula would also create a force inherently holding the tack and cannula together. Due to the inherency, it was not felt required to specify in the previous Office Action when it was clear how the examiner explained how bodily fluid was located in the space or when silicone was being used from the teaching reference.

In response to applicant's argument that the examiner did not address the limitation of "at least one positive surface feature" in the previous Office Action. It has been clarified in this Office Action, however in the previous it was stated that Cummings et al clearly anticipated the structure of applicant's claimed limitations. The reference character (12) was not even changed between the patent and the instant application.

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Therefore, there should have been no confusion in understanding what was being used as a positive surface feature.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

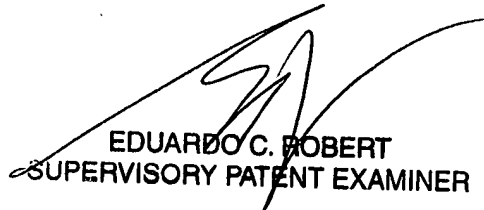


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
June 27<sup>th</sup>, 2006



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER